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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,438	09/01/2006	Esben Strobech	P71416US0	1786
136	7590	01/16/2008	EXAMINER	
JACOBSON HOLMAN PLLC			TREYGER, ILYA Y	
400 SEVENTH STREET N.W.				
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WASHINGTON, DC 20004			3761	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,438	STROBECH, ESBEN	
	Examiner	Art Unit	
	Ilya Y. Treyger	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 September 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/ are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/11/2007</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-23 of US Application 10/591,438 filed 09/01/2006 are presented for examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 5, 6, 14-18, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (US 5,690,622).
2. In Re claim 1, Smith discloses a drainage bag for receiving bodily waste, the drainage bag comprises:

a water-impermeable inner bag (1);

a gas impermeable outer bag (2) comprising an outlet 18 with a filter for releasing flatus gases from the outer bag;

a coupling system (A, C, D) for attaching the bag to the body of a patient and for securing the outer bag 2 in relation to the patients' body and for securing the outer bag in relation to the inner bag 1, the coupling system defining an orifice 6 to enable bodily waste to be received by the inner bag; and

a barrier 16 for preventing liquids and solid particles from passing from the inner bag to the outer bag, at least part of the barrier being permeable to flatus gases (See Abstract, ln. 1-16; Col. 3, ln. 44-48; Figs. 2 and 4).

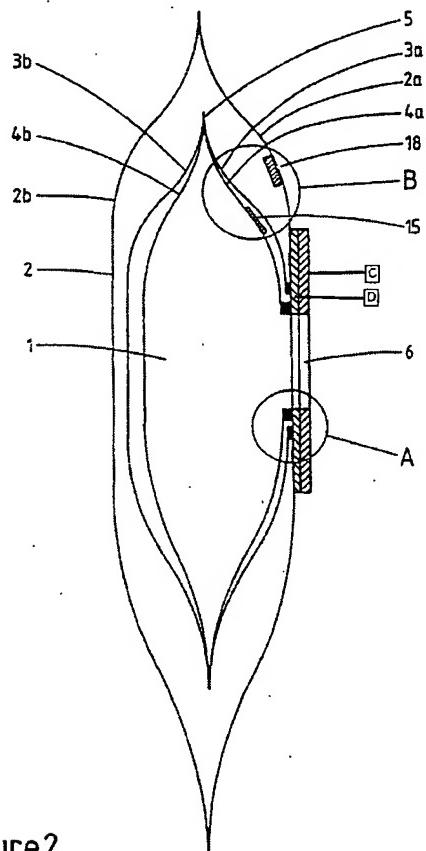


Figure 2

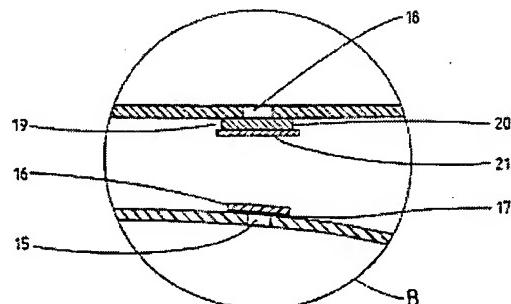


Figure 4

3. In Re claim 2, Smith discloses the inner bag impermeable to flatus gases (See Col 1, ln. 45-48). The disposition of the opening such as to allow flatus gases within the inner bag to pass out designates that the inner bag is impermeable to flatus gases.
4. In Re claim 3, Smith discloses the barrier comprising a gas permeable foam (See Col. 3, ln. 47-48).

5. In Re claim 5, Smith discloses means for forcing the flow of flatus gasses along a predetermined flow path (See Col. 1, ln. 45-48). The opening disposed such as to allow flatus gases within the inner bag to pass out performs the function of the claimed means.
6. In Re claim 6, Smith discloses the inner bag formed of the material rapidly soluble in the water (See Col. 3, ln. 3-4), what means that it maintains the integrity before it has been placed in the water.
7. In Re claim 14, Smith discloses a drainage bag for receiving bodily waste, the drainage bag comprises:
 - a water-impermeable inner bag (1);
 - a gas impermeable outer bag (2) comprising an outlet 18 with a filter for releasing flatus gases from the outer bag;
 - a coupling system (A, C, D) for attaching the bag to the body of a patient and for securing the outer bag 2 in relation to the patients' body and for securing the outer bag in relation to the inner bag 1, the coupling system defining an orifice 6 to enable bodily waste to be received by the inner bag; and
 - a barrier 16 for preventing liquids and solid particles from passing from the inner bag to the outer bag, at least part of the barrier being permeable to flatus gases (See Abstract, ln. 1-16; Col. 3, ln. 44-48; Figs. 2 and 4),
wherein the inner bag formed of the material rapidly soluble in the water (See Col. 3, ln. 3-4) what means that it maintains the integrity before it has been placed in the water.

8. In Re claim 15 and 16, Smith discloses the inner bag soluble in hot water, i.e. the inner bag maintains its limpness and buoyance upon immersion in the water (See Col. 3, ln. 3-5), since both limpness and buoyance of the bag can be presented until the bag exists only.

9. In Re claim 17, Smith discloses the inner bag, which dissolves or disintegrates within 30 seconds at 50° C. in water, but at 38° C. is only very slowly soluble (See Col. 3, ln. 3-5).

10. In Re claim 18, Smith discloses the biodegradable inner bag (See Col. 1, ln. 6-7; Col. 3, ln. 9-10).

11. In Re claim 23, Smith discloses the ostomy system wherein the coupling system comprises a gas-permeable hydrophobic foam material for preventing liquids and solid particles from passing from the inner bag to the outer bag, at least part of the barrier being permeable to flatus gasses (See Abstract, ln. 1-16).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,690,622).

15. In Re claim 7, Smith discloses an ostomy system wherein the coupling system comprises a body flange C defining a central opening 6 and the barrier 15 (See Fig. 2).

Smith does not expressly disclose the barrier member coextending with the central opening of the body flange.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to move the barrier member to position coextending with the central opening 15 of the body flange as claimed, because such modification would reduce the gas pressure in the inner bag.

It has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (**MPEP 2144.04 (VI-C)**).

16. In Re claim 8, Smith discloses the invention discussed above wherein the coupling system comprises an outer flange D attached to the body flange defining a central opening 6 which coextends with the central opening of the body flange;

the inner bag 5 being sealed to an outer surface of the outer flange, so that flatus gases may only escape from the inner bag through the barrier 15; and

the outer bag 2 arranged such that flatus gasses escaping the inner bag through the barrier enter the outer bag (See Fig. 2).

Smith does not expressly disclose the outer flange attached to an outer surface of the barrier.

The rationale of obviousness rejection discussed above in claim 7 is incorporated herein in it's entirety.

17. In Re claim 9, Smith discloses the claimed invention, except the overlapping the barrier by the outer flange of the coupling system.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to overlap the barrier by the outer flange, because this is the only mechanical option to combine the opening of Smith with central opening as claimed.

18. In Re claim 10, Smith discloses the claimed invention discussed above, as applied to claim 7, but does not expressly disclose the surface layer comprising at least one perforation allowing flatus gases to inter the barrier at the first portion thereof and to exit the barrier at the second portion thereof, whereby flatus gases may escape from the inner bag.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the barrier foam with the gas-impermeable perforated surface layer because such modification would make the barrier sealable and in the same time to allow flatus gases to follow claimed direction.

19. In Re claim 11, Smith discloses the claimed invention, except for perforation provided as a non-coated surface extending partially into first portion of the barrier and partially into second portion of the barrier layer.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the perforation provided as a non-coated surface extending

partially into first portion of the barrier and partially into second portion of the barrier layer because non-coated parts of surface are equal to perforations in the layer. And extending the perforation into both portions of the barrier layer is the only way to provide moving of flatus gases in the claimed direction.

20. In Re claim 12, Smith discloses the claimed invention discussed above, as applied to claim 10, except for plurality of perforations, at least one of which is provided at the first portion of the outer surface of the barrier, and at least another one of which is provided at the second portion.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the surface layer with plurality of perforations because this modification would provide even distribution of durability of the barrier.

It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8 MPEP 2144.04 (VI-B).

21. In Re claim 13, It would have been obvious to one having ordinary skill in the art at the time the invention was made to angularly displace the perforation at the first portion of the outer surface of the barrier with respect to the perforation at the second portion and to provide the barrier with the partial abstraction to flatus gases arranged between the perforation in the first portion and the perforation in the second portion because this modification would allow flatus gases to follow claimed direction and in the same time to have sealable or/and adhesively part of it's surface.

22. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,690,622) in view of Olsen (US 5,840,073).

Smith discloses the claimed invention discussed above, as applied to claim 1, but does not expressly disclose the barrier comprising a gas permeable membrane.

Olsen teaches that it is known to use gas permeable membrane in the ostomy bags (See Col. 2, ln. 50-51).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ostomy bag of Smith with the gas permeable membrane, as taught by Olsen, because such modification would improve the barrier features to liquids and solid particles.

23. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,690,622) in view of Smith et al. (US 5,591,144).

Smith '622 discloses the claimed invention discussed above, as applied to claim 1, but does not expressly disclose the material of the inner bag comprising 35-55% of starch.

Smith '144 teaches that it is known to use starch in material for the inner ostomy bag (See Col. 3, ln. 3).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ostomy bag of Smith '622 with the starch, as taught by Smith '144, because such modification would reduce the rustle noise of the bag during the use.

The specific range of the percentage of the starch in the inner bag material depends of the level of rustle noise desired/expected and therefore is the matter of optimization.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233(MPEP 2144.05 (II-A)).

24. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,690,622) in view of Smith (US 5,938,647).

Smith '622 discloses the claimed invention discussed above, except for the material of the inner bag comprising 35-55% by weight of synthetic polyester.

Smith '647 teaches that it is known to use synthetic polyester in material for the inner ostomy bag (See Col. 2, ln. 24).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inner bag of Smith '622 with the polyester, as taught by Smith '647, because such modification would allow to make a bag capable to maintain its physical integrity.

The specific range of the percentage of the polyester in the inner bag material depends of the level of flexibility desired and therefore is the matter of optimization.

The rationale of obviousness rejection discussed above in claim 19 is incorporated herein in it's entirety.

25. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,690,622) in view of Smith et al. (US 5,591,144), as applied to claim 19 above, and further in view of Smith (US 5,938,647).

Smith '622 in view of Smith '144 disclose the claimed invention, but does not disclose the use of the starch with polyester in the material of the inner ostomy bag.

Smith '647 teaches that it is known to use synthetic polyester in material for the inner ostomy bag (See Col. 2, ln. 24).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inner bag of Smith '622/Smith '144 with the polyester, as taught by Smith '647, because such modification would allow to reach a desirable level of the rustle noise and flexibility of the bag.

The particular value of both components depends of the level of flexibility and level of rustle noise required and therefore is a subject of optimization.

It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (**MPEP 2144.05 (II-B)**).

26. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 5,938,647), as applied to claim 14 above, in view of Coombes (US 4,917,689).

Smith discloses the claimed invention, except for the material of the inner bag comprising not more than 10% by weight of a softener, such as glycerol.

Coombes teaches that it is known to use a glycerol in the ostomy bag material (See Col. 2, ln. 33-34).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inner bag of Smith with the glycerol, as taught by Coombes, because such modification would improve the comfort level for the wearer.

The particular percentage of the glycerol in the material of the colostomy bag depends of the comfort level desired and therefore is the subject of optimization.

The rationale of obviousness rejection discussed above in claim 19 is incorporated herein in it's entirety.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,902,551 disclose the OSTOMY APPLIANCE WITH BARRIER MEMBER HAVING A SINGLE COUPLING RING WITH TWO COUPLING AREAS FOR CONNECTION OF INNER AND OUTER BAG MEMBERS. US 7,087,042 disclose the OSTOMY APPLIANCE AND METHOD OF USE. US 4,300,560 disclose the OSTOMY BAG HAVING A BOTTOM DRAIN VALVE. US 5,248,308 disclose the OSTOMY POUCH COVER. US 6,231,553 disclose the COLOSTOMY BAG.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ilya Y. Treyger whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
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SUPERVISORY PRIMARY EXAMINER

